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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/748,642	12/22/2000	Thomas B. Albrecht	026.00041	4973
35876	7590	02/17/2004		
ROGALSKY & WEYAND, LLP P.O. BOX 44 LIVONIA, NY 14487				
			EXAMINER LACOURCIERE, KAREN A	
			ART UNIT 1635	PAPER NUMBER

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/748,642

Applicant(s)

ALBRECHT ET AL.

Examiner

Karen A. Lacourciere

Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 December 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 12-18-2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1,6-9,14-16 and 18.

Claim(s) withdrawn from consideration: 2-4 and 10-12.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.


10. ☐ Other: \_\_\_\_\_

Karen A. Lacourciere

Continuation of 2. NOTE: Applicant's amendments have incorporated the limitations of claims 18 into independent claims 7 and 15, which limits the claimed methods to specific viruses. Claim 18 was previously dependent on a canceled claim and these specific viruses were not specifically considered. Applicant's amendments would require further consideration under 35 USC 112, first paragraph as to the enablement of the claimed method for these specific viruses. Further, Applicant's amendments change the dependency of claims 6 and 14, to limit claims 7 and 15 (respectively) to specifically inhibiting the protease calpain, however, claims 7 and 15 are already limited to calpain inhibitors and new considerations would need to be made as to whether an objection should be made over a failure to further limit the parent claims.

Continuation of 3. Applicant's reply has overcome the following rejection(s): If entered, Applicant's reply would overcome the rejection of record under 35 USC 102(b) of claims 1 and 9 as anticipated by Roizman, the rejection of record under 35 USC 112, second paragraph of claim 18 and the rejection of record of claims 1, 9 under 35 USC 112, first paragraph because these claims have been canceled.

Continuation of 5. does NOT place the application in condition for allowance because: In response to the rejection of record of claims 1, 6-9 and 14-16 under 35 USC 112, first paragraph, as lacking enablement, applicant argues that the specification demonstrates that calpain cleaves p21Cip1, which is necessary for activation of E kinase, which in turn is critical for efficient HCMV replication and that treatment of virally infected cells with protease inhibitors and measurement of the resultant viral infection is known in the art. nt argues that given this knowledge, the skilled artisan may need to undergo some experimentation but that the experimentation would not be undue. These arguments have not been found to be persuasive. The specification presents very limited examples that do not address the scope of the methods claimed, which are directed to methods of treatment and methods of inhibiting viruses other than HCMV. These are methods that are recognized in the art as unpredictable, as discussed in the rejection of record, and calpain inhibitors are recognized in the art as ineffective for inhibiting the replication of some viruses, as discussed in the rejection of record. Applicant's arguments are directed to determining the ability of a protease to inhibit the replication of a virus in cells in culture, but do not support the enablement of the methods of treatment claimed or inhibiting viral replication for the broad scope of viruses claimed.

  
KAREN A. LACOURCIERE, PH.D.  
PRIMARY EXAMINER